

1 Sustained release formulations containing acetaminophen and tramadol

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Abstract

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5 A sustained release formulation as a unit dose contains 100 mg – 1000 mg of
6 Acetaminophen and 15 mg – 150 mg of tramadol hydrochloride, which comprises of 1)
7 an immediate release portion comprising of 25% - 75% of the total effective amount of
8 drug in the dosage form and 2) a sustained release portion comprising of a) 25% - 75%
9 of the total effective amount of drugs in the dosage form; b) 6% - 50% of gelling
10 polymers of the total formulation, and c) optionally an enteric coating at a level of 5% -
11 40% of the total formulation. The set forth formulation dissolves 25% - 60% of the total
12 drug in the first hour, 50% - 90% of the total drug in the first four hours and not less than
13 80% of the total drug in the first 12 hours using USP dissolution method II at 50 rpm.

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26 Inventors: 1. Zhang, Shuyi (Parsippany, NJ)

27 2. Wang, Jin (Cedar Grove, NJ)

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